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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/715,284 | 11/17/2003 | Hashem Akhavan-Tafti | Lumigen 4.1-88 | 5215 |
| 23700 | 7590 | 01/10/2006 | EXAMINER | |
| LUMIGEN, INC. 22900 W. EIGHT MILE ROAD SOUTHFIELD, MI 48034 | | | GROSS, CHRISTOPHER M | |
| | | | ART UNIT | PAPER NUMBER |

1639

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,284

Applicant(s)

AKHAVAN-TAFTI ET AL.

Examiner

Christopher M. Gross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6, 7, 13-21 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 8-12, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/19/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-26 are pending. Claims 3,6,7,13-21,24-26 are withdrawn. Claims 1,2,4,5,8-12,22 and 23 are examined herein.

Priority

2. This application has a filing date of 11/17/2003. Applicant makes no claim for the benefit of any prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c).

Information Disclosure Statement

3. The information disclosure statement filed 8/19/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. References T and U have been placed in the application file, but the information referred to therein has not been considered.

Election/Restrictions

4. Applicant's election without traverse of group C (C1-C20 alkyl, aralkyl, or aryl quaternary phosphonium salt) for species i, the nucleic acid binding moiety, group C (a silica matrix) for species ii, the solid-support and group A (the cleavable linker portion is cleaved hydrolytically) for species iii-a, the chemical mechanism of cleavage in the reply filed on 10/3/2005 is acknowledged.

Claims 3,6,7,13-21,24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable

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generic or linking claim. Election was made **without** traverse in the reply filed on 10/3/2005.

Claims 1,2,4,5,8-12,22 and 23 are examined herein.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 8, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kausch, et al (US Patent 5665582 - IDS entry 8/19/2005).

Claim 1 is drawn to a solid-phase for binding nucleic acids comprising: (i) a solid-support, (ii) cleavable linker, (iii) nucleic acid binding portion. Claims 8, 9 and 10 represent variations thereof.

Kausch et al throughout the publication, especially column 4, lines 58-65, figure 2, and the abstract disclose glass and polymeric (optionally magnetic) beads which bind chromosomes or other biological material. The system of Kausch et al comprises a reversible (capable of depolymerization) polymer, bearing pendant reversible (capable of dissociation from the biological material) linkers. The reversible linker acts as an temporary interface between the reversible polymer and chromosomes.

The chromosome of Kausch et al reads on the preamble nucleic acid of claim 1. The glass or polymer beads of Kausch et al read on the solid-supports of claim 1 as well as the silica matrix of claim 8. The magnetic option of Kausch et al reads on the magnetically responsive portion of claim 10. The reversible polymer of Kausch et al reads on the cleavable linker of claim 1 (ii). The reversible linker interface of Kausch et

al. reads on the nucleic acid binding portion of claim 1 (iii). The LCAA in figure 2 of Kausch et al refers to a long chain alkyl amine spacer, reading on the one or more connecting portions of claim 9.

6. Claims 1, 8, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Summerton, et al (US Patent 6060246 - IDS entry 8/19/2005).

Claim 1 is drawn to a solid-phase for binding nucleic acids comprising: (i) a solid-support, (ii) cleavable linker, (iii) nucleic acid binding portion. Claims 8, 9 and 12 represent variations thereof.

Summerton et al throughout the publication, and especially column 2, lines 42-49, figure 1, and column 9 line 33 disclose silica beads which bind nucleic acids, comprising a cleavable linker bearing N-morpholino oligonucleotide probes capable of Watson-Crick base pairing with an analyte of interest.

The analyte of Summerton et al reads on the preamble nucleic acid of claim 1. The silica particles of Summerton et al read on the solid-support of claim 1 (i) and the silica matrix of claim 8. The cleavable linkage of Summerton et al reads on the cleavable linker of claim 1 (ii). The N-morpholino oligonucleotide probes of Summerton et al. reads on the nucleic acid binding portion of claim 1 (iii). The polyethylene chains in figure 4 of Summerton et al read on the one or more connecting portions of claim 9. Summerton et al disclose esters as a cleavable linker, reading on claim 12.

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7. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lough, et al (US Patent 5900481).

Claim 1 is drawn to a solid-phase for binding nucleic acids comprising: (i) a solid-support, (ii) cleavable linker, (iii) nucleic acid binding portion. Claims 8 is drawn to a solid-support composed of silica.

Lough et al throughout the publication, and especially column 5, lines 18-31 and column 3, lines 25-26 and figures 3 and 4 disclose silica beads which bind nucleic acids with a cleavable linkage.

The amino modified oligonucleotide of Lough et al in figure 3 read on the preamble nucleic acid or nucleic acid binding portion of claim 1 (iii). The trityl cleavable linkage shown in figure 3 of Lough et al read on the cleavable linker of claim 1 (ii). The silica beads of Lough et al read on the solid-support of claim 1 (i) and the silica matrix of claim 8.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,2,4,8,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hughes** (1996 Tetrahedron Letters 37: 7595-7598) and **Lough et al** (US Patent 5900481).

Claim 1 is drawn to a solid-phase for binding nucleic acids comprising: a solid-support, cleavable linker, and nucleic acid binding moiety. The **elected species** comprises a solid-support composed of silica, a hydrolytically cleavable linker and an aralkyl quaternary phosphonium salt nucleic acid binding moiety is reflected in claims 2,4,8 and 11.

Hughes, teaches throughout the publication and especially in scheme 2 and footnote 13, hydrolysis of an aralkyl quaternary phosphonium ylide (salt) from a solid matrix.

Hughes does not teach silica as the solid support, however. Furthermore, Hughes does not teach the support for binding of nucleic acids.

Lough et al teach throughout the publication, and especially column 3, lines 25-26 silica as a support for binding nucleic acids.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made, to employ the chemistry developed by Hughes with the nucleic acid binding silica beads of Lough et al.

One of ordinary skill in the art would have been motivated to make and use the chemistry of Hughes with the silica beads of Lough et al to take advantage of the chemical versatility afforded by orthogonal nucleic acid binding, as noted by Lough et al on page in column 5 lines 18-31.

One of ordinary skill could do so with a reasonable expectation of success since silica immobilized phosphonium salts are well known in the art.

9. Claims 1,2,4,5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Tundo et al** (1982 JACS 104: 6551-6555) and **Lough et al** (US Patent 5900481).

Claim 1 is drawn to a solid-phase for binding nucleic acids comprising: a solid-support, cleavable linker, and nucleic acid binding moiety. Claims 2,4,5 and 8 represent variations thereof.

Tundo, et al teaches throughout the publication and especially in Table 1 silica derivatized with a tributylphosphonium salt which is taken to be the solid phase of claim 5.

Tundo et al does not teach the support for binding of nucleic acids, however.

Lough et al teach throughout the publication, and especially column 3, lines 25-26 silica as a support for binding nucleic acids.

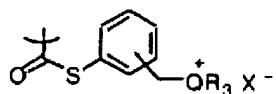
It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made, to use the tributylphosphonium derivatized silica of Tundo et al for nucleic acid binding per Lough et al.

One of ordinary skill in the art would have been motivated to make and use the beads of Tundo with the system of Lough et al to take advantage of the chemical versatility afforded in orthogonal nucleic acid binding, as noted by Lough et al on page in column 5 lines 18-31.

One of ordinary skill could do so with a reasonable expectation of success since silica immobilized phosphonium salts are well known in the art.

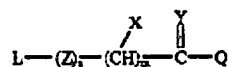
Claims 1 and 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Roberts et al** (US Patent Application Publication 2003/0158333) and **Lough et al** (US Patent 5900481).

Claim 1 is drawn to a solid-phase for binding nucleic acids comprising: a solid-support, cleavable linker, and nucleic acid binding moiety. Claims 22 and 23 are drawn a solid-phase comprising the structure:



wherein Q is P or N and R is alkyl of 1-20 carbons.

Roberts, et al teaches throughout the publication and especially in claim 1, block polymers terminated with a thioester group having, for example, the following structure:



wherein Z=a [bead] linker, X=H, Y=O, Q=S-R1, and R1=a substituted aryl.

Roberts et al does not teach the support for binding of nucleic acids, however.

Lough et al teach throughout the publication, and especially column 3, lines 25-26 various supports capable of for binding of nucleic acids.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made, to use the polymer of Roberts et al as part of the nucleic acid binding beads per Lough et al.

One of ordinary skill in the art would have been motivated to make and use the block polymers of Roberts et al with the system of Lough et al to take advantage of the chemical versatility afforded in orthogonal nucleic acid binding, as noted by Lough et al on page in column 5 lines 18-31.

One of ordinary skill could do so with a reasonable expectation of success since derivitization of beads with block polymers is will known in the art.

Conclusion

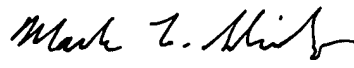
10. Claims 1,2,4,5,8-12, 22 and 23 are not allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher M Gross
Examiner
Art Unit 1639


Mark Shibuya
Examiner
Art Unit 1639